PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	15.01.98

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
DCW	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB96/02802	14/11/1996	14/11/1995

Applicant
KCI MEDICAL LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
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Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference DCW	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (PCT/IPEA/416)
International application No. PCT/GB96/02802	International filing date *(day/month/year)* 14/11/1996	Priority date *(day/month/year)* 14/11/1995
International Patent Classification (IPC) or national classification and IPC A61M27/00		
Applicant KCI MEDICAL LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06/06/1997	15.01.98
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Form PCT/IPEA/409 (Cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB96/02802

I. **Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-9 as originally filed

Claims, No.:

1-6 as received on 29/11/1997 with letter of 26/11/1997

Drawings, sheets:

1/5-5/5 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (**Rule 70.2(c)**):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 1-6
	No:	Claims
Inventive step (IS)	Yes:	Claims
	No:	Claims 1-6
Industrial applicability (IA)	Yes:	Claims 1-6
	No:	Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

SECTION V

1. The closest prior art document as regards the subject-matter of claim appears to be WO-A-94/20041.

This document discloses, see page 12, line 8 to page 18, line 35 and figs. 1, 8-11, a therapeutic apparatus for stimulating the healing of a wound in mammals which comprises a porous pad (10), which is permeable to liquids for introduction into the wound, a dressing (18) for covering the wound and providing a substantially air-tight seal around the wound, a drainage conduit (12, 36) connecting the pad (10) to a suction pump (40) so that the suction can be applied to the wound to draw fluids therefrom, said conduit (12, 36) being connected to the pump (40) via a canister (28,33) for collecting liquids sucked from the wound and a filter barrier (38a) located between the canister (28,33) and the suction pump (40).

As regards the feature concerning the filter barrier being located between the canister and the suction pump, particular reference is made to fig. 8 and the description on page 16, lines 13-20 and page 18, lines 9-27 of said document.

1.1 The subject-matter of claim 1 differs from this dis closure in that it comprises an additional conduit connecting the porous pad to pressure detecting means, whereby the pressure substantially at the wound site may be monitored.

Therefore the subject-matter of claim 1 is new and the claim meets the requirements of Art. 33(2) PCT.

1.2 However this feature is suggested for the same purpose in DE-A-4 306 478.

In particular this document discloses, see fig. 5 and the description on col. 3, lines 24-43 and col. 5, lines 56-65, an apparatus for draining fluids from a body comprising in particular, besides a drainage conduit (52) connected to a suction pump, an additional conduit (54) connecting the area from which the fluid is drained to pressure detecting means (90). By applying the closing means (94) to the proximal end of conduit (54) it is possible to detect the pressure at the drainage area in order to regulate the drainage suction.

Therefore the subject-matter of claim 1 does not involve an inventive step and does not meet the requirements of Art. 33(3) PCT.

1.3 The device described in claim 1 is industrially manufacturable and therefore the claim meets the requirements of Art. 33(4) PCT.

2. Claims 2 to 6 depend from claim 1 and refer to further embodiments of the matter of said claim. Therefore claims 2 to 6 meet the requirements of Art. 33(2) and (4) PCT for the same reasons mentioned at points 1.1 and 1.3 above.

2.1 The features of claims 2 and 3 are disclosed for the same purpose in said DE-A-4 306 478, see abstract.

2.2 The features of claim 4 are disclosed for the same purposes, as regards the suction pump and canister being contained in a housing adapted to be worn and controls located on an upper side of the housing, in US-A-4 710 165, see abstract, drawings and col. 5, lines 33-40, and as regards the housing having a curved side intended to be supported against the body in WO-A-80/02182, see figures and abstract.

2.3 Claim 5 specifies that:

a) the filter barrier is located in the canister at the outlet side, and

b) pressure detecting means are arranged to detect the pressure changes in the drainage tube between the canister and the pump to signal a pressure change when the liquid in the canister covers a substantial part of the filter barrier, thus indicating a full canister.

However, feature a) is disclosed for the same purpose in the document GB-A-2 220 357, see page 8, lines 2-16 and fig. 1, and feature b) is disclosed for the same purpose in DE-U-295 04 378, see the whole document.

2.4 The feature of claim 6 is disclosed for the same purpose in WO-A-94/20041 (and also in GB-A-2 220 357 and DE-U-2 950 4378.

Therefore claims 2 to 6 do not involve an inventive step and do not meet the requirements of Art. 33(3) PCT.

SECTION VII

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document WO-A-94/20041 is not mentioned in the description, nor is this document identified therein.

2. The description does not disclose the invention as claimed and is thus not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

3. The independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the relevant prior art documents being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

   The features which are known in combination from the relevant prior art document (see WO-A-94/20041) and belong in the preamble the claim are indicated in section V, point 1, while the features which are not disclosed in said documents and should have been indicated in the characterizing portion are indicated at point 1.1 of said section.

   If, however, the two-part form were considered to be inappropriate, the description should have been amended so as to ensure that it is clear therefrom which features of the subject-matter of the independent claims are known from the closest prior art documents (see the PCT Guidelines PCT/GL/3 III, 2.3a).

CLAIMS:-

1. Therapeutic apparatus for stimulating healing of a wound in mammals which comprises a porous pad, which is permeable to liquids for introduction into the wound, a dressing (102) for covering the wound and providing a substantially air-tight seal around the wound, a drainage conduit (101) connecting the pad to a suction pump (6) so that suction can be applied to the wound to draw liquids therefrom, said conduit being connected to the pump via a canister (100) for collecting liquids sucked from the wound and at least one filter (109) interposed between the canister and the pump, said apparatus including an additional conduit (106) connecting the porous pad to pressure detecting means (108) whereby the pressure substantially at the wound site can be monitored.

2. Apparatus as claimed in claim 1 which includes a relief valve (8) for admitting air to the additional conduit (106) and means for controlling the operation of the valve so that intermittent suction can be applied to the wound site.

3. Apparatus as claimed in claim 1 or 2 in which a single tube (126) links the porous pad with the housing, said tube being longitudinally partitioned to provide a drainage conduit (127 or 606) for applying suction and an additional conduit (130 or 607) for connection to said pressure detecting means.

4. Apparatus as claimed in any one of the preceding claims wherein the suction pump and canister are contained in a housing (210) adapted to be worn and wherein the housing has a curved side (211) intended to be supported against the body and has controls (214) located on an upper side (212) of the housing.

5. Apparatus as claimed in any one of the preceding claims wherein said filter is located in the canister at the outlet side and pressure detecting means (105) are arranged to detect pressure changes in a conduit (103) connecting the

canister and the pump and to signal a pressure change when liquid in the canister covers a substantial part of the filter, thus indicating a full canister.

6. Apparatus as claimed in claim 5 wherein the filter covers the entire outlet from the canister and the dimensions of the pores in the filter are such that when liquid covers substantially the whole of the filter, said pressure detecting means (105) signals a sharp increase in negative pressure in the conduit (103), connecting the canister with the pump.